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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,501	05/23/2001	Robert P. Kimberly	UAB-14402/22	9412

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Ellen S Cogen
Gifford Krass Groh Sprinkle Anderson & Citkowski
Suite 400
280 N Old Woodward Avenue
Birmingham, MI 48009-5394

EXAMINER
SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,501	KIMBERLY, ROBERT P.	
	Examiner	Art Unit	
	Jehanne E Souaya	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *23 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) ~~1-32~~ 1-21, 24-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) ~~1-32~~ 1-21, 24-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: "Notice to Comply" and "CRF Problem Report".

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claims 1, 2 and 20 are linking for groups I-V

Group I, claim(s) 3 and 11, drawn to a method for determining autoimmune disease or cancer susceptibility by haplotyping an individual in a Fas ligand promoter region directed to a polymorph which is active in binding NF-IL6 transcription factor.

Group II, claim(s) 4, 5, 10, and 12, drawn to a method for determining autoimmune disease or cancer susceptibility by haplotyping an individual in a Fas ligand promoter region directed to a polymorph which is active in binding TCF/LEF-1.

Group III, claim(s) 5 and 7, drawn to a method for determining autoimmune disease or cancer susceptibility by haplotyping an individual in a Fas ligand promoter region directed to a polymorph at position -756.

Group IV, claim(s) 5 and 8, drawn to a method for determining autoimmune disease or cancer susceptibility by haplotyping an individual in a Fas ligand promoter region directed to a polymorph at position -478.

Group V, claim(s) 5 and 9, drawn to a method for determining autoimmune disease or cancer susceptibility by haplotyping an individual in a Fas ligand promoter region directed to a polymorph at position -205.

Group VI, claim(s) 6, drawn to genotyping a Fas ligand promoter to identify susceptibility to a disease.

Claim 13 is linking for groups VII-X:

Group VII, claim(s) 14, drawn to a Fas ligand promoter polymorph which is –844 C/T.

Group VIII, claim(s) 15, drawn to a Fas ligand promoter polymorph which is –756 A/G.

Group IX, claim(s) 16, drawn to a Fas ligand promoter polymorph which is –478 C/T.

Group X, claim(s) 17, drawn to a Fas ligand promoter polymorph which is –205 C/6.

Group XI, claim(s) 18-19 and 21, drawn to primers and kits for Fas ligand promoter.

Group XII, claim(s) 24-26 and 31, drawn to a method for determining autoimmune disease or cancer susceptibility by haplotyping a Fas promoter, and further to methods wherein the polymorph is -690.

Group XIII, claim(s) 24-26 and 31, drawn to drawn to a method for determining autoimmune disease or cancer susceptibility by haplotyping a Fas promoter, and further to methods wherein the polymorph is -95.

Group XIV, claim(s) 27 and 28, drawn to a Fas promoter single nucleotide polymorph which is –690 T/C or greater than –660 or less than –680.

Group XV, claim(s) 27 and 29, drawn to a Fas promoter single nucleotide polymorph which is –95 G/A or greater than –660 or less than -680.

Group XVI, claim(s) 30, drawn to kits for Fas promoter.

Group XVII, claim(s) 32, drawn to genotyping Fas promoter polymorphisms for determining susceptibility to a disease.

2. The inventions listed as Groups I-XVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Firstly, the claims encompass products, for example claim 13 is directed to a single nucleotide, which are known in the art. Secondly, the structure and function of the Fas promoter and the Fas ligand promoter are different such that they do not share the same or corresponding special technical feature, thus polymorphisms, primers and kits to Fas ligand promoter are patentably distinct from polymorphisms, primers and kits to Fas promoter, as are methods of detecting polymorphisms in Fas ligand promoter different from methods of detecting polymorphisms in Fas promoter. Thus groups I-XI are patentably distinct from groups XII-XVII.

Groups I-V are patentably distinct from each other and groups XII-XIII are patentably distinct from each other because they are drawn to methods that detect different polymorphisms. Each polymorphism results in a nucleic acid sequence that is both structurally and functionally different.

Groups I-V are patentably distinct from group VI because the method of groups I-V require haplotyping a Fas ligand promoter, that is determining the nucleotide sequence at certain

positions, while the method of group VI requires determining the nucleotide sequence at two dissimilar genotypes and quantifying susceptibility of disease. The steps required to perform the methods are different.

Groups XII-XIII are patentably distinct from group XVII because the method of groups XII-XIII require haplotyping a Fas promoter, that is determining the nucleotide sequence at certain positions, while the method of group XVII requires determining the nucleotide sequence at two dissimilar genotypes and quantifying susceptibility to disease. The steps required to perform the methods are different.

Groups VII-X are patentably distinct from each other and groups XIV-XV are patentably distinct from each other because they are drawn to different polymorphisms which result in nucleic acid sequences that are both structurally and functionally different.

The claims drawn to polymorphisms (claims 13-17 and 27-29) are structurally and functionally distinct from the claims drawn to primers and kits (claims 18, 19 and 30). Further these products can be used to encode proteins which is not required to practice the invention of claims drawn to haplotyping or genotyping (claims 1-12, 20 and 24-26, 31-32).

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Sequence Listing

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). A computer readable form (CRF) of the sequence listing was submitted. However, the CRF could not be processed by the Scientific and Technical Information Center (STIC) for the reason(s) set forth on the attached CRF Diskette Problem Report.

5. Applicant should note that a complete reply to this office action must address both the Restriction requirement as well as the attached "Notice to Comply".

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Primary Examiner
Art Unit 1634
9/5/03